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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/589,674	04/03/2007	Markus Graf Matuschka-Greiffenclau	DEBE:068US/10609441	9938

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EXAMINER	
MACAULEY, SHERIDAN R	
ART UNIT	PAPER NUMBER
1651	

NOTIFICATION DATE	DELIVERY MODE
10/27/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/589,674	MATUSCHKA-GREIFFENCLAU ET AL.	
	Examiner	Art Unit	
	SHERIDAN R. MACAULEY	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 August 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18* is/are pending in the application.

4a) Of the above claim(s) *1-17* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. A response and amendment were received and entered on August 2, 2010. All evidence and arguments have been fully considered. Claims 1-18 are pending. Claims 1-17 are withdrawn from further consideration due to a previous requirement for restriction. Claim 18 is examined on the merits in this Office action.

Claim Objections

2. Claim objections are withdrawn due to amendment.

Claim Rejections - 35 USC § 112

3. Rejections under 35 USC 112, second paragraph, have been withdrawn due to amendment.

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claim 18 stands rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

6. The claim recites a method of affecting alcohol degrading process in respect to ethanol metabolism within the human body, comprising administering to a subject the food composition or dietary supplements of claim 1 (a composition comprising the following substances in physiologically relevant amount: dextrose, vitamin C, L-glutamine, cysteine, riboflavin, succinic acid, and/or fumaric acid, and coenzyme Q10), wherein said method has the following effects within the human body: reducing ethanol metabolism by slowing down the process of ethanol oxidation into acetaldehyde, to prevent accumulation of acetaldehyde; stimulating the activity of ALDH and avoiding any blockade of its enzymatic activity; speeding up the reaction from acetaldehyde to acetic acid and further decomposition in the citrate cycle; and improving the levels of those anti-oxidants of the alcohol consumer which specially protect against toxic effects of acetaldehyde.

7. In making a determination as to whether an application has met the requirements for enablement under 35 U.S.C. 112 ¶ 1, the courts have put forth a series of factors. See, In re Wands, 8 USPQ2d 1400, at 1404 (CAFC 1988); and Ex Parte Forman, 230 U.S.P.Q. 546 (BPAI 1986). The factors that may be considered include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. Id. While it is not essential that every factor be examined in detail, those factors deemed most relevant should be considered. In the instant case, those factors deemed most relevant are the amount of

direction or guidance presented, the presence or absence of working examples and the nature of the invention.

8. The disclosure is not enabling for a method for affecting alcohol degrading processes in respect to ethanol metabolism in a human body, wherein the method has the effects recited in the claims, because it does not present enough direction and guidance for one skilled in the art to use the invention with a reasonable expectation of success without undue experimentation. The disclosure does not provide any guidance or working examples to direct one to perform the method recited in the claim on a human in order to achieve the result recited in the claims. The working examples disclosed in the instant application are directed to the formulation of the composition and the various benefits that the elements of the composition may provide. Although applicant has provided experimental evidence directed to the actual administration of the composition recited in the claims to a human patient (see declaration under 37 CFR 1.132 filed on August 2, 2010), no evidence is provided to demonstrate that the various components of the composition would confer the specific effects described in the claims when administered to a human patient. As set forth under the heading "Response to Declaration" below, the working examples of applicant declaration demonstrates that the composition affects alcohol metabolism, but does no demonstrate that alcohol metabolism is affected as described in the claims, such as by reducing ethanol metabolism by slowing down the process of ethanol oxidation. Further, the nature of the invention is such that a specific range of benefits would be expected as a result of the practice of the method. There are no findings in the specification to demonstrate that the

results recited in the claims would occur upon administration of the composition of the claims. Given these facts, one skilled in the art would be unable to predict whether the claimed method could be performed with a reasonable expectation of success.

9. Therefore, the disclosure of the instant application does not enable one skilled in the art to practice the invention as claimed.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

11. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

12. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was

not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

13. Claim 18 stands rejected under 35 U.S.C. 103(a) as being unpatentable over Popp et al. (US 6,630,158; cited in prior action) and Amselem (US 5,989,583; cited in prior action). The claim recites a method of affecting alcohol degrading process in respect to ethanol metabolism within the human body, comprising administering to a subject the food composition or dietary supplements of claim 1 (a composition comprising the following substances in physiologically relevant amount: dextrose, vitamin C, L-glutamine, cysteine, riboflavin, succinic acid, and/or fumaric acid, and coenzyme Q10), wherein said method has the following effects within the human body: reducing ethanol metabolism by slowing down the process of ethanol oxidation into acetaldehyde, to prevent accumulation of acetaldehyde; stimulating the activity of ALDH and avoiding any blockade of its enzymatic activity; speeding up the reaction from acetaldehyde to acetic acid and further decomposition in the citrate cycle; and improving the levels of those anti-oxidants of the alcohol consumer which specially protect against toxic effects of acetaldehyde.

14. Popp teaches methods for the administration of supplements comprising dextrose (glucose), vitamin C, L-glutamine, cysteine, riboflavin and coenzyme Q-10 to humans (col. 3, lines 1-25 and 46-67, col. 7, lines 61-67). The reference does not teach the inclusion of succinic acid or fumaric acid in the compositions for use in the methods taught therein.

15. Amselem teaches supplements comprising succinate and that succinate is a useful additive in compositions comprising coenzyme Q-10 to lessen oxidation of the compound (col. 6, line 62-col. 7, line 9).

16. At the time of the invention, the administration of compositions comprising nearly all of the claimed elements was known, as taught by Popp. The inclusion of succinate in a composition comprising coenzyme Q-10 in such a composition was also known, as taught by Amselem. One of ordinary skill in the art would have been motivated to combine these teachings to arrive at the claimed method by including succinate in the composition of Popp because Amselem teaches that succinate is a useful additive in compositions comprising coenzyme Q-10 to lessen oxidation. Although the references do not teach the claimed effects on alcohol metabolism within the human body, since the compositions of the prior art contain all of the claimed elements, any effects of the claimed invention would be inherent to the method of the combined prior art. One of ordinary skill in the art would have had a reasonable expectation of success in performing the combined method because Popp teaches that the compositions are suitable for administration to humans and Amselem teaches that succinate is compatible with such a composition. It would therefore have been obvious to one of ordinary skill in the art to combine the teachings discussed above to arrive at the claimed invention.

Response to Declaration

17. The declaration under 37 CFR 1.132 filed August 2, 2010 is insufficient to overcome the rejection of claim 18 based upon 35 USC 112, first paragraph as set forth in the last Office action because it refer(s) only to the system described in the above referenced application and not to the language in the claims of the application. Although applicant has shown that the composition used in the method recited in the claims affects alcohol metabolism, applicant has not shown that the method works as specifically described in the claims. For instance, applicant has not demonstrated that the claimed method is effective for the reduction of ethanol metabolism by slowing down the process of ethanol oxidation. The evidence in applicant's disclosure shows that, when administered the compound, the subjects had lower ethanol and acetaldehyde blood concentrations. This evidence does not support applicant's claim language, which recites that ethanol metabolism is slowed down by the claimed method. The reduction of blood alcohol does not support the conclusion that the method results in the slower rate of ethanol metabolism recited in the claims; it could easily be indicative of a faster rate of alcohol metabolism. Furthermore, applicant has supplied no evidence that the method stimulates ALDH activity and avoiding any blockade of enzyme activity or that the method speeds up the reaction from acetaldehyde to acetic acid. Thus, the declaration does not support the specific effects of the method recited in the claims. Therefore, there is no showing that the objective evidence of enablement is commensurate in scope with the claims. See MPEP § 716.

18. It is also noted that the declaration states, at p. 1, that a copy of the *curriculum vitae* of the undersigned is attached. This document has not been included in applicant's response.

Response to Arguments

19. Applicant's arguments filed August 2, 2010 have been fully considered but they are not persuasive. Applicant argues that the specification, in combination with applicant's declaration, provides enablement for the claimed invention. However, the evidence presented in the declaration has not been found to be commensurate in scope with the claims, as discussed under the heading "Response to Declaration" above.

20. Applicant further argues that the claimed invention is not rendered obvious by the teachings of Popp and Amselem. Specifically, applicant argues that Popp does not teach all of the elements of the claimed invention except for succinic acid; however, Popp teaches that all of these elements are useful in a composition for the promotion and maintenance of healthy skin. One of ordinary skill in the art would therefore have recognized that these elements could be combined in a single composition in order to achieve the results discussed in Popp. Furthermore, although applicant argues that one would need to pick and choose among the components recited in the reference, it is noted that the claimed method recites the administration of a composition wherein the composition comprises a number of elements. One of ordinary skill in the art, when using the teachings of Popp to prepare a composition for skin health, need not pick and choose the specific components recited in the claims. Rather, one may choose to

prepare a composition comprising all of the components taught by Popp or a composition comprising several dozen of the components taught by Popp in order to arrive at the composition recited in the claims. Therefore, applicant's argument has not been found to be persuasive.

21. Applicant also argues that the composition of Popp is used in a different method than that recited in the claims, specifically that the method of Popp is for the promotion and maintenance of healthy skin whereas the claimed method is for affecting alcohol metabolism. However, although the references do not teach the claimed effects on alcohol metabolism within the human body, since the compositions of the prior art contain all of the claimed elements, any effects of the claimed invention would be inherent to the method of the combined prior art. Thus, applicant's argument has not been found to be persuasive.

22. Applicant further argues that one of ordinary skill in the art would not be motivated to combine the teachings of Amselem with those of Popp because Amselem is directed to the addition of succinate (in the form of alpha-tocopherol succinate, which would dissociate into succinic acid and alpha-tocopherol when in solution) to a lipid composition, whereas, applicant states, the composition of Popp is not taught to comprise lipids. It is noted that the compositions of Popp may be formulated to comprise a lipid (see Popp at col. 8, lines 35-50, where the use of oils such as corn or castor are described). Further, since coenzyme Q10 is a lipophilic substance, one of ordinary skill in the art would have been motivated to formulate a composition comprising this component in the presence of a lipid, and would therefore have been motivated to

combine the components taught by Amselem in order to prevent the formation of oxidative degradation products. Therefore, applicant's argument has not been found to be persuasive.

23. Thus, applicant's arguments have been fully considered, but they have not been found to be persuasive.

Conclusion

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHERIDAN R. MACAULEY whose telephone number is (571)270-3056. The examiner can normally be reached on Mon-Thurs, 7:30AM-5:00PM EST, alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SRM
/Ruth A. Davis/
Primary Examiner, Art Unit 1651